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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,230

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Hiroyuki Sato

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EXAMINER

MESH, GENNADIY

ART UNIT

PAPER NUMBER

1763

NOTIFICATION DATE

DELIVERY MODE

07/21/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/593,230	Applicant(s) SATO ET AL.	
	Examiner GENNADIY MESH	Art Unit 1763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1.1. Applicant's Amendment filed on July 6, 2011 is acknowledged.

Claims 3-4, 6-7 and 9 had been canceled. Claims 1,2,5,8 and 10 are active. No amendments to claims have been made in this amendment.

1.2. Rejection is maintained as it was set forth in preceding Office action mailed on March 18, 2011. Consequently, it is proper to make this action Final.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1-2, 5, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeProspero (US 3,565,869 - reference cited by Applicant) combined with Yamane et al. (US 2003/0125431) and in further view of Terado et al. (US 6,528,617).

2.1. Regarding Claims 1-2, 5, 8 and 10 DeProspero disclosed process for producing polyglycolic acid, substantially free from as residual glycolide and content of other volatile impurities below 0.2% (see abstract and column2, lines 60 - 63) by subjecting solid particles of polyglycolic acid to solid state heat treatment with heated and dried (moisture and oxygen free) inert gas (see Abstract) at temperature from 20 °C to 190 °C and reduced pressure- see column 3, lines 14 - 34.

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DeProspero is silent regarding the step of adding heat stabilizer during pelletizing of polyglycolic acid particles and additional step of heat treatment under **normal pressure**, as it required by amended claim 1, but DeProspero points out that heat treatment conducted at higher pressure will require longer time and lower contact temperatures in order to reduced impurities due to instability and degradation of fine particles of polyglycolic acid (see DeProspero column 4, lines 4-29).

However, Yamane, teaches that (see [0021]) "When the method in which heat history is applied to polyglycolic acid and the method in which the heat stabilizer is added to crystalline polyglycolic acid is used in combination, a polyglycolic acid composition modified in thermal properties and moreover improved in melt stability can be provided".

Therefore, it would be obvious to one of ordinary skill to add heat stabilizer to polyglycolic acid per teaching of Yamane in order to increased thermal stability of the polyglycolic acid obtain by process disclosed by DeProspero.

2.2. As explain above DeProspero combined with Yamane is silent regarding additional heat treatment step at conducted at normal pressure.

However, Terado teaches solid phase polymerization of aliphatic polyester with following additional heat treatment step, under flow of gas at normal pressure in order to minimized residual monomer content below 1000 ppm (see column 2, lines 50 - 60 , column 3, lines 35 -65 and Examples) or remove any volatility from polymer.

Therefore, it would be obvious to one of ordinary skill in the art to add additional step of heat treatment at flow of gas at normal pressure per teaching of Terado in order

to decrease residual cyclic ester below 1000 ppm in process disclosed by DeProspero combined with Yamane.

Regarding limitation of Claims 8 and 10 related to particle size - see DeProspero column 4, lines 18 - 33.

Response to Arguments

4. Applicant's arguments with respect to claims 1-3, 5, 7, 8 and 10 have been fully considered but they are not persuasive.

5. Applicant's arguments related to Claims 1-2, 5, 8 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over DeProspero (US 3,565,869 - reference cited by Applicant) combined with Yamane et al. (US 2003/0125431) and in further view of Terado et al (US 6,528,617) based on following statements:

a) First, the process of DeProspero already achieves a residual glycolide content of less than 0.2% (see col. 3, lines 34-44). Therefore, the reference provides no reason or rationale for a person of ordinary skill in the art to add an additional heat treatment to the PGA product in order to obtain a residual glycolide content of less than 0.2 %.

Regarding this argument note, that one of ordinary skill will be motivated reduce presence of glycolide content of less than 0.2 % and even to lesser amount, because as explained by DeProspero (see column 2, lines 38 - 45) presence of " undesirable glycolide and other impurities" made polymer unsuitable for medical applications.

Regarding rational to add additional heat treatment to process disclosed by DeProspero see paragraph 2.2. above.

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b) Second, paragraph [0021] of Yamane et al. teaches the application of heat history to PGA within a temperature range "higher than the melting point T_m thereof, but not higher than ($T_m + 100\text{ }^{\circ}\text{C}$)". As a result, the reference teaches the heat treatment to PGA that is in a molten state. On the other hand, claim 1 recites "then contacting the pelletized aliphatic polyester with a flowing heated dry gas under normal pressure", and thus the heat treatment in the process of claim 1 is applied to a PGA that is in a pelletized solid state.

It should be noted, that Applicant cited only one, incomplete sentence from paragraph [0021] of Yamane with out rational provided by Examiner in Office action.

However, Yamane, teaches that (see [0021]) "When the method in which heat history is applied to polyglycolic acid and the method in which the **heat stabilizer** is added to crystalline polyglycolic acid is used in combination, a polyglycolic acid composition modified in thermal properties and moreover improved in melt stability can be provided".

Thus, Yamane provided teaching related to heat stabilization by adding heat stabilizer in melt (same as done by Applicant), which is different than "then contacting the pelletized aliphatic polyester with a flowing heated dry gas under normal pressure" as argued by Applicant.

Therefore, this Applicant's argument is not persuasive.

c) Third, Terado et al. states "However, in the aliphatic polyester of the present invention, the content of lactide is 1000 ppm or less [i.e., less than 0.1%] at the time before the heat treatment, and therefore the improvement of thermal stability resulted in by the heat treatment according to the present invention is not achieved by removal of lactide" (see col. 2, lines 39-44). In fact, however, the reference further teaches a post-treatment of an aliphatic polyester obtained after solid phase polymerization in the presence of a volatile catalyst, such as an organic sulfonic acid, by a solid-state heat treatment under a flowing gas to provide improved thermal stability by removal of the volatile organic catalyst.

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This Applicant's argument is not persuasive, because Terado teaches heat treatment process as claimed by Applicant. Note, that any volatile components will be intrinsically removed during any this treatment. In addition, language of Applicant's claims does not exclude organic acid catalyst used by Terado. Therefore, one of ordinary skill will be guided by Terado to perform additional heat treatment to minimize any volatile impurities in polymer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272 1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MILTON I CANO/
Supervisory Patent Examiner, Art Unit 1763

Gennadiy Mesh
Examiner
Art Unit 1763

/GM/